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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-668B and CMS-1557]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS) is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. Type of Information Collection Request: Extension of a currently approved collection. Title of Information Collection: Post Clinical Laboratory Survey Questionnaire and Supporting Regulations in 42 CFR 493.1771, 493.1773, and 493.1777. Use: Form CMS-668B is used by a Clinical Laboratory Improvement Amendments (CLIA) laboratory to express its satisfaction with the survey process and to make recommendations for improvement. Surveyors furnish this form to all laboratories that receive either an onsite survey or the Alternate Quality Assessment Survey (i.e., paper survey of quality indicators). CMS Central Office performs an

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overview evaluation of the completed forms. Each calendar year, a summary of the information collected is sent to the State and CMS Regional Office. Form Number: CMS-668B (OCN 0938–0653). Frequency: Biennially; Affected Public: Business or other for-profits and not-for-profit institutions. State, Local, or Tribal Government, Federal Government. Number of Respondents: 21,000. Total Annual Responses: 10,500. Total Annual Hours: 2,625. (For policy questions regarding this collection contact Kathleen Todd at 410–786–3385. For all other issues call 410–786–1326.)

2. Type of Information Collection Request: Extension of a currently approved collection. Title of Information Collection: Survey Report Form for Clinical Laboratory Improvement Amendments (CLIA) and Supporting Regulations in 42 CFR 493.1–493.2001.

Use: CMS 1557 is used to report surveyor findings during a CLIA survey. For each type of survey conducted (i.e., initial certification, recertification, validation, complaint, addition/deletion of specialty/subspecialty, transfusion fatality investigation, or revisit inspections) the Survey Report Form incorporates the requirements specified in the CLIA regulations. Form Number: CMS–1557 (OCN 0938–0544). Frequency: Biennially. Affected Public: Business or other for-profit, Not-for-profit institutions, State, Local or Tribal Governments and Federal Government. Number of Respondents: 21,000. Total Annual Responses: 10,500. Total Annual Hours: 5,248. (For policy questions regarding this collection contact Kathleen Todd at 410–786–3385. For all other issues call 410–786–1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web Site address at http://www.cms.hhs.gov/PaperworkReductionActof1995, or E-mail your request, including your

address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov, or call the Reports Clearance Office on (410) 786-1326.

In commenting on the proposed information collections please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in one of the following ways by [OFR—insert date 60] days after date of publication in the Federal Register]:

- Electronically. You may submit your comments electronically to
 http://www.regulations.gov.
 Follow the instructions for "Comment or Submission" or "More
 Search Options" to find the information collection document(s) accepting comments.
 - 2. By regular mail. You may mail written comments to the following address:

CMS, Office of Strategic Operations and Regulatory Affairs

Division of Regulations Development

Attention: Document Identifier/OMB Control Number _____

Room C4-26-05

7500 Security Boulevard

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Dated: <u>January 31, 2012</u>

Martique Jones,

Director, Regulations Development Group, Division B

Office of Strategic Operations and Regulatory Affairs.

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